SYNOPSIS

ON

AWARENESS AND PERCEPTION OF CONSUMERS AND CHEMISTS TOWARDS GENERIC MEDICINES: A STUDY OF HARYANA

For registration

In

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1. INTRODUCTION

1.1 Demography of india:-

India with around 1.38 billion population ranks 2nd in terms of population and shares 17.71% of the total population burden of the world. 34.5 % of the population of India is urban and 65.5% resides in the rural india (worldometer). 41.1% of the population in india ages below 18 years and 47.9% are as young as less than 21 years of age. Basically the age of more than 50% of the indian population is below 25 years and over 65% are below the age of 35, According to the government data available at the government website (official data the census of india 2011). Rangarajan committee found that 29.5 percent of total population lived below poverty line in India during 2011-2012. World bank report of 2006 stated that 34.7 % of Indians earn less than US$ 1 per day and majority of them worked in unorganized sector with an average salary of less than 0.5 $ per day.

1.2 India: "The pharmacy of the world":-

India has been referred to as the pharmacy of the low-income and middle-income countries (Jack A. 2012). Ensuring equitable access to essential medical products, vaccines and technologies of assured quality, safety, efficacy and their scientifically sound and cost-effective use is an important function of a well performing health system. The Indian pharmaceutical industry is the third largest in the World in terms of volume and tenth largest in terms of value India is the largest provider of generic drugs globally. Access to affordable HIV treatment from India is one of the greatest success stories in medicine. India is one of the biggest suppliers of low-cost vaccines in the world. Because of low price and high quality, Indian medicines are preferred worldwide, thereby rightly naming the country "the pharmacy of the world" (Bigdeli, M. et al. 2013).

The Pharmaceutical sector currently contributes around 1.72% to the country's GDP as per the annual report 2019-20 of ministry of chemicals and fertilizers, department of pharmaceuticals (government of india). However, several essential medicines remain inaccessible within India especially for the poor, due to policy and implementation failures in ensuring access (Bhargava

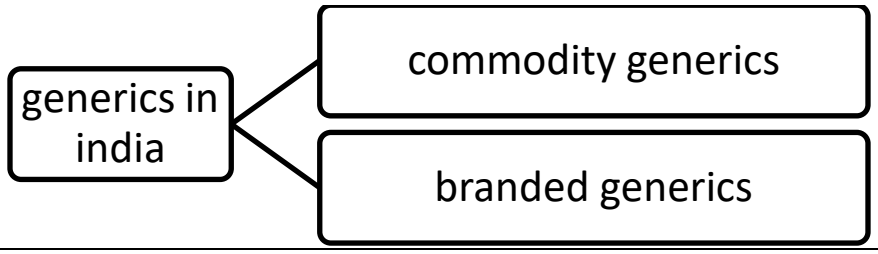
A et. al, 2020). In India, healthcare delivery is provided either by government agencies or private entities. The Government provides healthcare through Primary Healthcare Centres (PHC) and limited secondary and tertiary care institutions (Creeze A. et al, 2007). The rural India is predominantly served by primary healthcare centres. Patients in developing countries bear 80 percent of healthcare expenses from their pockets, of which 70 percent are for medicines (Francisquinho, A. M. N. (2013). Health Insurance of any kind that covered rural population stood at 14.1 percent and 18.1 percent in urban India as per The Economic Times. according to The Economic Times Around 40% of Indians live on less than Rs. 72 per day and one of the major payouts is for healthcare purpose. So, the question is that is there any way by which these out-of-pocket expenses of the patients can be mitigated to the maximum possible extent yes, there exists alternative medication to the branded medicines which could cost 20-90% lower than their branded bioequivalent. Generic Medicines are an important though suspicious substitute for the branded medicine to reduce the out-of-pocket expenditures on Medicines however the attitude and perception about these Medicines raise issues of the confidence and trust in these Medicines, and also these variables play a crucial role while developing the marketing strategy for these Medicines.

1.3 Generic medicines

Generics is a term, which is used in a number of different contexts, primarily three. A drugs generic name is the pharmacological name of the compound assigned either by WHO's International Non-proprietary Names Committee or by the US Adopted Name Council. Drugs whose patents have expired are also included in the category of generics.

"Generic medicines can be defined as replicas of brand name drugs with the same quantities, effects and side effects, way of administration, risks and safety and as strength as the original medicine; which mean that the pharmacological effects are the equal as those from brand name medicines. Generic medicines have the same active substances as the original medicine, whose intellectual property rights, relating to the active substances or manufacturing process have expired and are therapeutic equivalents of those, not only because they have the same qualitative and quantitative composition but also because they have the same pharmaceutical form.

Sometimes generic medicines may have different colours, flavours or different inactive ingredients than the original branded medicine. Although by law generics should have the same active ingredients. Nevertheless, law does not specify anything more about generic formulation, which means that inactive ingredients can be changed in order to adjust pill size, colour, and the same properties like how much time it will be needed for the pill to dissolve in the stomach. Each manufacturer has its own variation of the inactive properties" Francisquinho, A. M. N. (2013). It is clear from the above explanation the only difference between a brand name drug and a generic is that brand name drugs are sold by proprietary name and are very expensive due to the advertisement cost, while generics are far cheaper and are sold by just the pharmaceutical salt name. This holds true for brand name drugs and generics in most western developed countries. In the developed countries, branded drugs researched and patented first-in-market. After the expiry of patent period, other companies launch generics of the innovator drug with just the pharmaceutical salt name at a hugely discounted price. In many developing countries such as India, there is another category called 'branded generic' which is so named to distinguish from generics. Branded generics are off patent drugs with same active substances as the original medicine.



in india:- copies of patented drugs in the erstwhile process patent regime in India were loosely termed as generic copies of patented drugs. Generic drugs are broadly classified into commodity generics and branded generics. Commodity generics, which have been on the market since 1950s are simply generic name products marketed by a wide variety of companies. Branded generics are either unpatented drugs sold under a brand name or patent-expired products sold under a generic name prefixed by the company's initial(s)- a practice which helps differentiation from other generic manufacturers and is supposed to provide an assurance of quality.

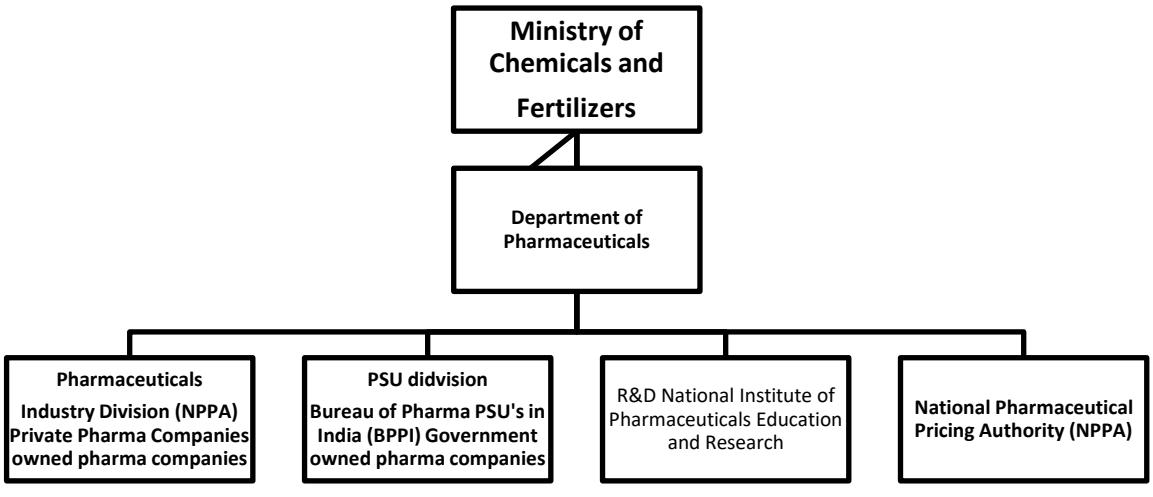
1.4 History and Regulation of the generics:-

The history and evolution of generic medicines can be traced to the history of drug discovery, drug patents, and use. The most significant drug discoveries started in the late 18th century. The concept of patent arrived in the early 19th century. However, only few manufacturers chose to get the process patent for their products. The history of the world's earliest and most successful patent can be traced to Aspirin, which was launched in 1899 by Bayer's pharmacological laboratory (Marko V., 2020)

1.5 Regulation: Global vs. Indian context context:-

On September 24, 1984, in the 98th United States Congress, the act named The Drug Price Competition and Patent Term Restoration Act was passed, informally known as the Hatch-Waxman Act, encouraging the manufacture of generic drugs by the pharmaceutical industry and established the modern system of government generic drug regulation in the United States (Kelly, C., 2011).

On October 2012, Government of India issued a direction that the drugs will be sold within a generic name instead of their brand names (Economic Times). Department of Pharmaceuticals (DoP) under the Indian central government supplies generic medicines by procuring them from public sector companies.

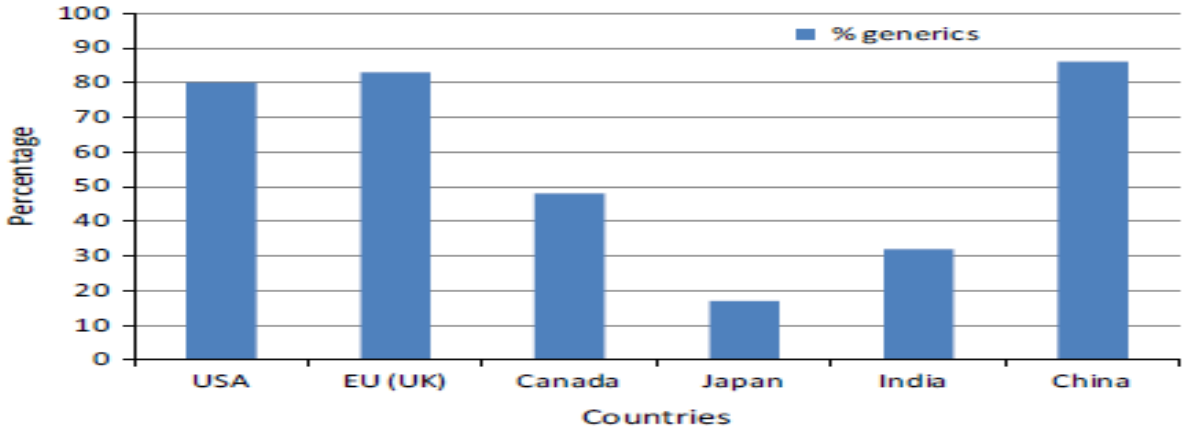

Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals
Pharmaceuticals
Industry Division (NPPA)
Private Pharma Companies owned pharma companies
PSU didvision
Bureau of Pharma PSU's in India (BPPI) Government owned pharma companies
R&D National Institute of Pharmaceuticals Education and Research
National Pharmaceutical Pricing Authority (NPPA)

Regulatory Framework of the Pharmaceutical Industry in India

Source: Annual Report 2016-17 Department of Pharmaceuticals

1.6 Use of generics in india in comparison with some other nations:-

The use of generic medicines has been increasing all over the world, due to the economic advantages they offer. Prescription audits have shown that the percentage of medications prescribed by generic names varies from below 50% in India, Canada, Japan, and African countries to over 80% in countries such as USA, UK, China, and Australia.



Percentage of medicines prescribed by generic names in different countries.

Generic drug manufacturers do not have to spend extra money for drug discovery and preclinical and clinical trials. Generics are available at a lower cost; they provide an opportunity for savings in drug expenditure in a country.

1.7 Pharmaceutical Market in india:-

India's generic drug producers hold a strong position in the global supply chain and play an integral role in developing the pharmaceutical industry. Some of the major domestic players in the industry include Sun Pharmaceutical Industries, Cipla, Lupin, Dr. Reddy's Laboratories, Aurobindo Pharma, Zydus Cadila, Piramal Enterprises, Glenmark Pharmaceuticals, and Torrent Pharmaceuticals. India is the only country in the world that has the highest number of US FDA-approved plants for generic drug manufacturing (more than 262 including active pharmaceutical ingredients) outside the US. Some of the leading Indian pharma companies derive about 50 per cent of their turnover from exporting generic medicines to developed

markets like the US and Europe. India is a prominent and rapidly growing presence in global pharmaceuticals. It is the largest provider of generic medicines globally, occupying a 20% share in global supply by volume, and also supplies 62% of global demand for vaccines. India is the source of 60,000 generic brands across 60 therapeutic categories and manufactures more than 500 different Active Pharmaceutical Ingredients (APIs). The API industry is ranked third largest in the world contributing 57% of APIs to prequalified list of the WHO (Briefing, 2020).

20%	$19.3 Bn	70%	21%
Generics medicines exports share (global)	Pharma exports worth	Generic drugs revenue share	Patented drugs revenue share

(*Pharmaceutical Industry in India: Invest in Pharma Sector*, 2021)

1.9 Generics and treatment compliance:-

In the case of government health services, lack of trust can affect utilisation and in turn drive patients to the private sector, increasing out-of-pocket (OOP) expenditures. In the case of non-communicable diseases (NCDs), the need for long term and often lifelong treatment is associated with particularly high OOP spending. Patients with higher ability to pay for medicines are likely to continue taking medicines longer while poorer patients tend to forego or shorten treatment. Lowering medicine cost or providing medicines as a part of a universal health coverage strategy can improve treatment adherence, outcomes and improve quality of life (Aivalli, P. K. et. al., 2018). Similarly results has been reported in some other researches that patients suffering from chronic diseases when initiated on generic medicines show better adherence to the long-term treatment than those started on branded medicines, perhaps due to lower costs (Shrank, W. et al., 2006). Thus, along with the cost savings, generic medicines also improve patient compliance

1.9 Trust and health-seeking behavior:-

Health-seeking behaviour is influenced by various factors including patient satisfaction, competence of provider, perceived quality of care and patient experience, which in turn are affected by trust in the care provided (Hall, et. al., 2001). Trust in health systems and services is multidimensional and is conditioned by macrolevel factors such as health policy and overall public opinion about health providers and microlevel factors including individual perceptions

and experience. Vulnerability resulting from the experience of being ill often requires patients to place their trust in a trustee (in this case a healthcare provider), in the expectation of amelioration or cure. A positive result from this experience tends to facilitate the building of a trustful relationship which conditions future encounters. (C. A., 2016).

2. REVIEW OF LITERATURE

2.1 Knowledge about the concept of generics:-

Amongst the physicians and pharmacists: studies shows that physicians and pharmacists are aware of the potential of generic drugs in the improvement of global access to drugs. However, there are marked differences in how pharmacists and physicians consider the quality of generic drugs depending on the maturity of the healthcare system in their own country. This can be attributed to the fact that developed healthcare systems have more reliable public control routines for drugs in general as well as better bioequivalence requirements concerning generics in particular (Toverud, et. al , 2015).

Amongst patients or consumers: Literature shows that patients and medicine consumers tend to prefer original brand medicines over generic medicines. Further, in many countries, there is still a considerable proportion of patients and consumers who lack adequate knowledge or have insufficient information about generic medicines. Thus, there is a need for educational interventions and activities to educate patients about generic medicines. It is also evident in the literature that health care professionals (physicians and pharmacists) play a key role in the promotion of generic medicines and in patients' acceptance of generic medicines and generic substitution. Hence, health care professionals need to play a more active role by educating patients and recommending generic medicines to their patients. Other researches indicated that consumers had a reasonably positive perception towards generic drug substitution practices. Attitude towards generic drugs was the most important predictor of consumer perceptions towards generic drug substitution practices. This included their attitudes towards safety, efficacy, cost, side effects and therapeutic equivalency. Forty to fifty per cent of

participants did not consider generic drugs to be as safe and effective, or identical to a brand name drug (Sansgiry S. S., & Bhosle M. J. 2004). but the major limitation to this study is that it has been conducted in USA, again a developed country.

Cost benefits of generic drug substitutes: The use of generic medicines, compared to their branded counterparts, has the potential to substantially reduce out-of-pocket expenditure on drugs for patients with chronic diseases as per the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India. Generic substitution of brand prescriptions is an accepted practice in many parts of the world, and this is often done for economic reasons.

2.2 Reasons stated for the non-adoption of generic drugs in india:

Literatures have pointed out some fundamental reasons for the non adoption of generic drugs in india as as:

- Non-availability of generic formulations.
- Distrust of generic medicines by practitioners often due to perceived inferior quality and counterfeiting of drugs. (Billa, G . et. al. 2015).
- Lack of awareness and knowledge about the generic medicines.
- Safety and efficacy issues were viewed as major barriers to the acceptance of generic drug substitutions.

2.3 **Variables influencing majorly the uptake of generic drugs:** As per our literature review, which was focused on developed countries, consumer confidence and knowledge about generic medicines use have increased steadily over time. *Mass education efforts, financial incentives and greater communication between patients and health care professionals* were seen as major influences on the uptake of generics among consumers.

2.4 **Need of hour: role of government as a promoter or generic drugs**: In a country like India, there is a need for government intervention to make medicines

affordable. It is more in case of poor and vulnerable sections of our society. The private pharmaceutical industry cannot be expected to help the government in objectives of social good and welfare of the masses. The government cannot leave our population at the mercy of pharmaceuticals companies in the name of Free market economy, which simply calls some capital infusion from the centre's end in the pharma industry (Pareek M., & Prakash D. M. 2019). Trust in and relationship with providers as a determinant of health-seeking behaviour has been studied in Cambodia by Ozawa S, Walker DG and similar studies in india found that that patients chose their health facility based on their confidence and trust in healthcare providers.

2.5 **Views of researchers:** Researches suggest more research about consumers' views on generic drug products should be carried out in developing countries, where cost savings are needed more than in developed countries. This will enable them to contrast the findings with those from the developed world and to reach a universal view and researchers should consider further study of consumers' decision-making processes regarding generic medication. better communication among patients and health care professionals regarding the equivalency between most branded and generic products should increase the use of generic medications (Hassali, M. A. et. al. 2009).

2.6 **Consumption patterns and predictions about consumption behaviour:** Some studies only confined to the urban areas also suggest some points Effectiveness as other branded medicines, Doctor has a good opinion about the generic medicine, Lower prices, Quality and Owner of Pharmacy promoting leads to higher trust can be used as *predictor variables* to model the consumption of Generic Drugs. Patients who used generic drugs also recommended generic drugs to others which is a very important finding in this study. Hence based on the above results, it was evident that generic drugs can be promoted better using doctors, pharmacists and customer's word of mouth (Nagarajappa, M. H. 2020). Assurance from prescribers regarding the safety and efficacy of generic drugs may create a positive feeling among consumers, thus encouraging

generic drug use. Strong promotion of generic drugs at the prescriber's office may help increase generic drug utilisation.

2.7 **Reasons contributing to the divergent views regarding generic drugs:** In general, A review paper depicted that consumers showed mixed reactions towards the use of generic medicines and the paper taken under consideration reviewed 20 studies conducted in different developed nations. Eleven were from the USA, four were from Europe, two were from Canada and one each was from Australia, Brazil and Malaysia. This was evident from the divergence of views observed by country development level, consumers' socioeconomic characteristics, drug product characteristics, pharmaceutical reimbursement system, policy environment, contact with health care professionals, past experience with medications, and knowledge of the seriousness of a medical condition.

3. RESEARCH GAPS:-

- Wider systemic issues related to trust in public services and providers and how these could affect the utilisation of such schemes or services, are scarcely studied.

- No studies have been conducted taking into account the rural people (exclusively) as a consumer of generics and for checking their knowledge level, perception and access barriers to the drugs.

- Physicians’ and Pharmacists’ perceptions of generic drug use are not well documented

- Few studies mentions the supply chain gaps and barriers in the supply of these drugs to the general public through government route but here again no study examines these barriers as the core objective.

4. OBJECTIVES:-

1. To know the perception and awareness about the generic drugs amongst consumers;
2. To understand pharmacists' perceptions and willingness to recommend the generic medicines; and
3. To examine the consumption patterns of generic.

5. RESEARCH METHODOLOGY

A research problem may take several steps or statistical tools to find its solution, the researcher has to stick to these predefined steps to find a solution and these steps are defined within Research Methodology which provides a well-defined procedure and technique used to find solution for any research problem. How the data would be collected?, How the collected data would be analyzed? Are the main two questions answered in the research methodology.

Intense knowledge is the main necessity while drafting the research methodology for a research problem. A well-defined research methodology plays role of guide for researcher to find a solution and conclude it. hence, it plays a vital role in research problem.

5.1 Research Design

A research design is an integral part of research methodology and a blueprint for answering the research questions and fulfilling objectives. Social research needs a well-defined set of steps before data collection. A good research design enables the researcher to collect the evidences to get answer of the initial question as precisely as possible. The present study is exploratory in nature for farmers and extension officers in Haryana. Exploratory study will be used to explain the Attitude, impact, and Constraints in adoption of ICT among farmers. To make the study more reliable and accurate self-structured questionnaire will be used to conduct the study.

5.2 Research Universe

The universe of the study is Haryana. The Haryana state comprises twenty two districts. The respondent of the study are the consumers of medicines. The researcher will get information about awareness amongst respondents about the concept of generics, perception and how their perception affects access to medicines in government health facilities, the health seeking behaviour and impact of out-of-pocket expenditures on the medication course. Keeping in view the sample of the study, the Haryana state will be divided into six administrative divisions i.e. Ambala, Faridabad, Gurugram, Hisar, Rohtak, Karnal.

5.3 Sampling Design

The universe of the study is large enough and we cannot study all the units of universe, so we will choose sampling units from the universe. We will use multistage sampling technique to choose our sampling units. In the first stage, one district will be selected from each division. In second stage, out of selected district, two villages will be selected i.e. the nearest village and the farther most. In the last stage we will select 20 respondents from each villages. Further for the comparative study 40 respondents from each district will be selected, so as to compare the data inter and intra district. The sample size of the study is to be purposed to four hundred eighty but it can be increased or decreased according to the requirement of the study. Random cum convenience sampling will be used to reach the required sample of respondents from different group of respondents.

5.4 Data Collection

To achieve the objectives, required data will be collected from primary as well as secondary sources.

Primary data: Questionnaire will be prepared for the purpose of primary data collection.

Secondary data: The secondary data will be collected from various published sources like magazines, journals, newspapers and internet.

5.5 Statistical Tool

The data collected will be analysed and interpreted by applying need based statistical tools and techniques like percentage, mean, standard deviation, correlation, regression, exploratory factor analysis, confirmatory factor analysis and structural equation modelling (SEM).

5. ORGANIZATION OF THE STUDY

The study is proposed to be organized in following chapters:

Chapter 1: Introduction: In this chapter, conceptual framework and objectives of the study will be presented.

Chapter 2: Literature review: In this chapter, literature related to topic will be reviewed to support the present study. With the help of this review, research gap will be highlighted.

Chapter 3: Research Methodology: This chapter will provide a quick glance on the research process to be followed to achieve the objectives of the study. The chapter will also contain the information on all the statistical tools to be used for analysis and interpretation of data during the course of study.

Chapter 4: Analysis and interpretation: This chapter will be dealing with analysis of collected data to achieve the objectives of the study.

Chapter 5: Findings and recommendations: This chapter will summarize the major findings of the study. It will also provide some recommendations based on research findings, which is the goal of this research proposal.

Chapter 6: References: The purpose of a reference list is that the reader should be able to find the references used.

The above scheme of the study is tentative in nature. It may change as for the requirement of the study.

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